REMARKS

Reconsideration and allowance of the present application is respectfully requested in view of the foregoing amendments and the following additional remarks which have addressed all the issues raised in the May 03, 2005, Office Action or otherwise have rendered them moot.

Claims 36 - 44 and 67 are now under consideration in this application. Claims 45 – 66 stand withdrawn pursuant to Examiner's imposed restriction requirement. Claims 36, 40 and 41 have been amended. Claim 67 have been added. The claim amendments are in order to more particularly define and distinctly claim applicant's invention and/or to better recite or describe the features of the present invention as claimed. No new matter is believed to be added.

In the Office Action, the Examiner rejected claims 40 and 41 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention.

Also, the Examiner rejected claims 36, 37, 40 and 41 under 35 U.S.C. § 102(b) as allegedly anticipated by Itay (U.S. 5, 053, 050), in light of Thomas (1997, Taber's Cyclopedic Medical Dictionary, 18th Ed.), and Boden (1999, Clin. Orthop. 376:S84-S94).

Further, the Examiner rejected claims 38 and 42 under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of Johnson et al., (U.S. 4,156,296).

Also, the Examiner rejected claims 39, 43 and 44 under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36-38 and 40-42 above, and further in view of Wevers (U.S. 4,246,660).

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 40 and 41 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention. In the Examiner's assessment, "sized", and "configured", could all be considered either as verbs (thereby imparting an intended use limitation to the claims) or adjectives (thereby imparting structural limitations to the claims).

In response to the previous office action, Applicants amended the claims to use the phrase, "sized and configured" and advised the Examiner that the use of that prosecution-tested phrase "sized and configured" should obviate any alleged vagueness associated with "designed as". U.S. Patent number 6,860,070, in claims 1, 5, and 10, for instance, uses the complained of phrase, "size and configured."

Nevertheless, in the interest of advancing the prosecution of the current application, Applicants have amended claim 40 to recite a preformed construct suitable for the partial replacement of a joint surface comprising the biological joint construct according to claim 36. In that way, it becomes categorically clear that Applicants are claiming a preformed joint replacement construct fashioned out of their invention. Claim 41 merely adds shape limitation to the subject matter of claim 40 and additionally avoids the use of the phrase, "osteochondral cylinder" which the Examiner deemed indefinite.

By the foregoing amendments, Applicants believe that this ground for rejection has been adequately addressed and respectfully ask that it be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 36, 37, 40 and 41 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Itay (U.S. 5,053,050), in light of Thomas (1997, Taber's Cyclopedic Medical Dictionary, 18th Ed.), and Boden (1999, Clin. Orthop. 376:S84-S94). According to the Examiner, U.S. 5,053,050 teaches biological joint constructs produced at least partly in vitro, comprising a biocompatible carrier material and chondrocytes, which are implantable into defective bones. The Examiner further asserted that the broad nature of the claims is drawn to "any biological joint construct that, upon implantation, integrates into a bone and leads to the formation of layers of cartilage on the bone's end." Applicants disagree and respectfully traverse as follows.

A claim is anticipated under 35 U.S.C. §102(b) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *See Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Moreover, elements must be arranged as required by the claim. *See In re Bond*, 910 F.2d 831(Fed. Cir. 1990).

As stated in the instant specification, (page 1, lines 22-27) "U.S. 5,053,050 describes compositions for the repair of cartilage or bone, cartilage or bone cells being incorporated into a biological, resorbable carrier substance which contains serum, fibrinogen and thrombin." In particular, U.S. 5,053,050, describes the immobilization of chondrocytes or osteoblasts (column 3, lines 35 – 45) on a viscoelastic biodegradable matrix (column 4, lines 43-44), comprising serum, fibrinogen, thrombin, calcium chloride and aprotonin (column 2, lines 38-42).

Applicants continue to differ strongly with the Examiner's characterization of U.S. 5,053,050 as teaching a joint construct. As clearly stated in the specification of U.S. 5,053,050, it teaches a composition for the repair of cartilage or bone, said composition comprising chondrocytes or osteoblasts immobilized on biocompatible viscoelastic media. Although the viscoelastic composition of U.S. 5,053,050 may be poured into any geometric configuration in order to affect a repair of damaged tissue (column 4, lines 65-67), the term "joint construct" connotes a definite structural articulation which cannot reasonably be associated with the U.S. 5,053,050 patent. At least under 35 U.S.C. § 102(b), the elements of the '050 patent are not arranged as required by the claims of the present application. *See In re Bond*, 910 F.2d 831(Fed. Cir. 1990)

As made explicitly clear in the instant specification, the term *in vitro* "does not involve a joint construct grown naturally in the human or animal body" (page 3, lines 1-3). Instead, the joint construct of the present invention is produced partly in vitro. The Examiner indicated that she is constrained to give the broadest reasonable interpretation to the claims. However, Applicant has explicitly stated how the term "in vitro" is used. Thus the Examiner cannot ignore this definition and to do so will unreasonably broaden the claims.

Unlike U.S. 5,053,050 or any other art for that matter, the instant invention is directed to and encompasses the *in vitro* lateral sequestration of chondrocytes and/or chondroblasts on one side and osteoblasts and or osteocytes on the other side, prior to implantation in a damaged joint in order to affect a repair of both cartilage and bone. Said lateral sequestration is attained by immobilizing each type of cell in conjunction with the appropriate tissue substance on an appropriate biocompatible media (not necessary the same on both sides), such that the osseous and the cartilagineous sides are firmly connected.

The in vitro lateral sequestration of both types of cells and their appropriate tissue substances is not taught by the alleged prior art. Although the composition of U.S. 5,053,050

may use chondrocytes or osteoblasts, in vitro, either group of cells must be used disjunctively. See for example column 3, line 42 referring to a "population expressing a chondrogenic or osteogenic phenotype." This is so because U.S. 5,053,050 teaches the repair of either cartilage or bone and starts off with a composition of either chondrogenic cells or osteogenic cells in vitro but not both. In fact, it teaches in Example 1, column 4, lines 9-12, that starting off with chondrocytes, "[A]t 2 to 6 months all the implant below the osteochondral junction is transformed into bone while articular cartilage retains its cartilaginous properties." This at least amounts to a teaching that it is not necessary to start off with a joint construct having a lateral sequestration of chondrogenic or osteogenic cells, since chondrocytes below the osteochondral junction will be transformed to bone cells.

The Examiner recognizes that the *in vitro* lateral sequestration of chondrocytes and/or chondroblasts on one side and osteoblasts and or osteocytes on the other side, prior to implantation is not taught by U.S. 5,503,050, but insists that this limitation is not recited in the claims. Applicants maintain that that limitation is implicit in the claims via the Applicants' use of the phrase, "*in vitro*" as explicitly stated in the specification and as pointed out above.

Nevertheless, in order to advance the prosecution of this application, Applicants have amended independent claim 36, (and its dependents) to explicitly state that the structural articulation of the joint construct of claim 36 is formed prior to implantation. Therefore, for at least the fact that U.S. 5,053,050 does not teach the in vitro lateral sequestration of osteogenic and chondrogenic cells, prior to implantation, there is no basis for the rejection under 35 U.S.C. § 102(b). Applicants respectfully ask that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 38 and 42 stand rejected under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5,053,050), Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of Johnson et al., (U.S. 4,156,296). According to the Examiner's assertions in the previous office action, Johnson et al. teaches a joint construct that in anchored into the bone shaft with a cylindrical peg. As motivation for combining Johnson et al. and U.S. 5,053,050, the Examiner argued that a skilled artisan would appreciate that a peg articulated into a bone shaft would produce a more secure fit than would two flat ends touching. Regarding the reasonableness of

the expectation of success in combining Johnson et al. and U.S. 5,053,050, the Examiner asserted that U.S. 5,053,050 can be constructed in any shape or size (column 5, lines 3 -6).

Examiner noted that no amendments were made to these claims in an effort to overcome the rejection under 35 U.S.C. § 103(a). Applicants respectfully observe that claim amendments are not always necessary to overcome a rejection, especially, where as here, the Examiner has improperly given the claims the broadest interpretation not reasonably warranted by the language of the claims. In particularly, the Examiner was urged in the prior response to construe "in vitro" in accordance with the specific delineation of that phrase by the Applicant and not more. Here again, Applicants respectfully ask the Examiner to reconsider Applicant's use of the phrase "in vitro" in conjunction with the express limitation, "prior to implantation," and to weigh the proper construction of claim 36 and its dependent claims 38 and 42, against any combination of '050 which the Examiner asserts to be obvious.

Applicants hereby reiterate the arguments made in traversing the 35 U.S.C. § 102(b) above and particularly contend that a proper 103(a) rejection cannot be anchored on U.S. 5,053,050 based on the fact that the teachings of U.S. 5,053,050 differ fundamentally from the inventions of the present application as claimed and the deficiencies are not curable by the Examiner's combination.

In particular, U.S. 5,053,050 does not teach an in vitro lateral sequestration of chondrogenic and osteogenic cells prior to implantation to repair a damaged joint. Applicants contend that the endoprosthetic device made from non-biological materials as taught by Johnson et al. cannot be combined with U.S. 5,053,050 to arrive at the present invention comprising entirely biocompatible material. Even if as asserted by the Examiner, U.S. 5,053,050 can be fashioned on the basis of the teachings of '296 to have a peg shape, it is asserted that the putative combination teaches the in vitro use of either osteogenic cells or chondrogenic cells but not both immobilized on biocompatible viscoelastic material and indeed teaches away from the simultaneous use of osteogenic and chondrogenic cells laterally sequestered in vitro and firmly connected to one another.

Whereas '050 describes compositions for the repair of cartilage or bone wherein the cartilage or bone cells are incorporated into a biological, resorbable carrier substance which contains serum, fibrinogen and thrombin, any connection between osseous and cartilaginous tissues in the '050 case is formed only in vivo. Bone tissue grown in vivo is spongy, contains

bone marrow and is bound to differ micorstructurally from in vitro bone tissue. Similarly, in vivo cartilaginous tissue would necessarily differ microstructurally from in vitro cartilaginous tissue. The ability to fashion joint mimetic constructs in vitro, prior to implantation presents novel and unobvious features not taught by '050 or any combination of it. For at least the fact that the alleged combination does not teach the lateral sequestration of chondrogenic and osteogenic cells in vitro prior to implantation into damaged joints, there is no basis for the rejections under 35 U.S.C. § 103 (a). Applicants respectfully ask that these rejections be withdrawn.

Claims 39, 43 and 44 stand rejected under 35 U.S.C. § 103 (a) as allegedly obvious over Itay (U.S. 5, 053, 050), Thomas and Boden as applied to claims 36-38 and 40-42 above, and further in view of Wevers (U.S. 4,246,660) and Dunn et al., (1995, L. Biomed. Mater. Res. 29:1363). According to the Examiner neither 5,053,050 nor Johnson et al. teaches joint constructs or replacements with ligaments or joint capsules, said deficiencies being cured by Weavers et al and Dunn et al. Applicants respectively disagree and traverse as follows.

Applicants reiterate the arguments made in traversing the 35 U.S.C. § 102(b) above and particularly contend that a proper 103(a) rejection cannot be anchored on U.S. 5,053,050 based on the fact that the teachings of U.S. 5,053,050 differ fundamentally from the inventions of the present application as claimed and the deficiencies are not curable by the Examiner's combination.

In particular, U.S. 5,053,050 does not teach an in vitro, prior to implantation, lateral sequestration of chondrogenic and osteogenic cells prior to implantation to repair a damaged joint. Applicants contend that the prosthetic ligament device of Weavers comprising a plurality of interwoven parallel cord wrap elements cannot be combined with U.S. 5,053,050 to arrive at the present invention comprising entirely biocompatible materials.

Even if the Examiner insists on making the combination, it is again contended that U.S. 5,053,050 teaches the in vitro use of either osteogenic cells or chondrogenic cells but not both immobilized on biocompatible viscoelastic material and indeed teaches away from the simultaneous use of osteogenic and chondrogenic cells laterally sequestered in vitro and firmly connected to one another prior to implantation as now made explicitly clear in independent claim 36 from which claims 39, 43 and 44 depend.

For at least the fact that the alleged combination does not teach the lateral sequestration of chondrogenic and osteogenic cells in vitro, prior to implantation, there is no basis for the rejections under 35 U.S.C. § 103 (a). Applicants respectfully ask that these rejections be withdrawn.

CONCLUSION

All of the stated grounds for rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn and the claims allowed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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